

CLAIMS

1. A method of producing microparticles comprising a bioactive and a vehicle, which method comprises providing a solvent having a bioactive dispersed or dissolved therein and a vehicle dissolved therein, carrying out an emulsification in a non-solvent phase to produce an emulsion comprising the bioactive and the vehicle in a solvent phase, and evaporating the solvent to leave said microparticles, wherein a mixture of at least two surfactants is employed to stabilise said emulsion and the HLB (hydophilic-lipophilic balance) of the mixture is up to 8 in order that the median diameter of the microparticles is up to 100µm.
2. A method as claimed in claim 1, wherein said HLB is from 2 to 7.
3. A method as claimed in claim 1 or 2, wherein said HLB is from 3 to 5.
4. A method as claimed in any preceding claim, wherein said HLB is from 3 to 4.
5. A method as claimed in any preceding claim, wherein said mixture comprises sorbitan monoleate and sorbitan dioleate.
6. A method as claimed in any preceding claim, wherein said mixture is an equimolar mixture of two surfactants.
7. A method as claimed in any preceding claim, wherein the vehicle is a polymer which enables pH-dependent and/or pH-independent release of the bioactive in the gastrointestinal tract.
8. A method as claimed in any of claims 1 to 6, wherein the vehicle is a polymer which enables pH-dependent release of the bioactive in the gastrointestinal tract.

9. A method as claimed in any preceding claim, wherein the vehicle is an acrylic-based polymer, a cellulose-based polymer or a polyvinyl-based polymer.

5 10. A method as claimed in claim 9, wherein the vehicle is a methacrylate polymer.

11. A method as claimed in any preceding claim, wherein the vehicle comprises Eudragit ® L100, Eudragit ® L100-55, Eudragit ® S100, Eudragit ® P4135, Eudragit ® RS100 or ethylcellulose.

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12. A method as claimed in any of claims 1 to 8, wherein the vehicle is not Eudragit ® RS alone.

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13. A method as claimed in any preceding claim, wherein the bioactive is prednisolone, bendrofluazide or budesonide.

14. A method as claimed in any preceding claim, wherein the solvent is ethanol or a mixture of acetone and ethanol or methanol.

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15. A method as claimed in any preceding claim, wherein the surfactants in said mixture are both added to the solvent phase, both added to the non-solvent phase, or wherein one is added to each phase.

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16. A method as claimed in any preceding claim, wherein the non-solvent phase is liquid paraffin.

17. A method as claimed in any preceding claim, wherein the emulsification is carried out at a temperature from 10 to 30°C.

18. A composition of microparticles obtainable by means of a method as claimed in any preceding claim.
19. A method of medical treatment comprising administering to a patient an effective amount of microparticles as claimed in claim 18.  
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